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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/660,902	Applicant(s) SU ET AL.	
	Examiner Angela Bertagna	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

Remarks

Claims 1-30 were the subject of the non-final rejection mailed February 21, 2006. In response, claims 14 and 15 have been cancelled, and claims 27-30 have been withdrawn. Accordingly, claims 1-13 and 16-26 are pending.

Election/Restrictions

This application contains claims 27-30 drawn to an invention nonelected with traverse in Paper No. 20060527. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 22-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorre et al. (Bioimaging (1997) 5: 139-152) in view of Kneipp et al. (WO 99/44045).

Dorre teaches a single-molecule sequencing method based on the detection of fluorescent nucleotides released by sequential exonuclease digestion of an immobilized nucleic acid (see abstract, Figure 1 and pages 140-141).

Regarding claim 1, Dorre teaches

(a) immobilizing a fluorescently labeled nucleic acid molecule to a surface (page 140, col. 2)

(b) sequentially releasing the fluorescently labeled nucleotides from one end of the immobilized nucleic acid using exonuclease (page 140, col. 2)

(c) separating the released nucleotides from the exonuclease and the immobilized nucleic acid (page 140, col. 2)

(d) identifying the released nucleotides by fluorescence spectroscopy in a buffer comprising an alkali-metal halide salt (page 140, col. 2 – page 141, col. 1; see also page 144, col. 1, where the buffer includes $MgCl_2$)

(e) determining the sequence of the nucleic acid from the identified nucleotides (page 141, col. 2)

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Regarding claim 2, Dorre teaches that single nucleotides may be identified (page 140, col. 1).

Regarding claim 3, Dorre teaches sequencing of a single nucleic acid molecule (abstract).

Dorre teaches a single-molecule sequencing method based on the detection of fluorescent nucleotides released by sequential exonuclease digestion of an immobilized nucleic acid (see abstract, Figure 1 and pages 140-141).

Regarding claim 22, Dorre teaches

a) obtaining pyrimidine nucleotides that are attached to Raman labels (see 143, column 2, where dUTP and dCTP are attached to TMR and Cy5, respectively, where TMR and Cy5 are both Raman labels),

b) synthesizing a nucleic acid molecule comprising labeled nucleotides (see page 143, column 2),

c) removing nucleotides from one end of the nucleic acid (see page 144, column 1),

d) identifying the released nucleotides by fluorescence spectroscopy in a buffer comprising an alkali-metal halide salt (page 145, column 2; page 144, col. 2 teaches that the buffer includes MgCl_2)

(e) determining the sequence of the nucleic acid (see page 144, figure 5 and page 145, column 2).

Regarding claim 23, Dorre teaches that the alkali-metal halide salt is MgCl_2 .

Regarding claim 26, Dorre teaches synthesis of the DNA fragment to be sequenced by PCR amplification using a template, a primer and a DNA polymerase (see page 143, column 2).

Dorre does not teach using unlabeled nucleic acids, but rather fluorescently-labeled molecules. Also, Dorre teaches fluorescence rather than Raman spectroscopy, and does not explicitly teach simultaneous sequencing of multiple nucleic acids.

Kneipp teaches a method of nucleic acid sequencing using surface-enhanced raman spectroscopy (SERS) where single molecules of unlabeled nucleotides are detected (see page 15, 1st full paragraph; see also abstract). Kneipp particularly points out that Raman detection is preferable to fluorescence-based detection, since the need for a label is eliminated (page 12, line 27 – page 13, line 7).

Regarding claim 1, Kneipp teaches:

(a) sequentially releasing unlabeled nucleotides from one end of one or more nucleic acid molecules with an exonuclease (see all of page 15, in particular line 26 where exonuclease is used to remove “fragments” of DNA, line 18 where “each fragment comprises at least one base”; see also page 8, lines 4-9 which state that unlabeled nucleotides are analyzed and that single nucleotides may be detected)

b) separating the nucleotides from the exonuclease and the one or more nucleic acid molecules (page 15, lines 26-30)

c) identifying the unlabeled nucleotides by Raman spectroscopy (page 15, line 30-page 16, line 2 where the “spectral information” is defined on page 14, lines 29-30 as being obtained using Raman spectroscopy)

d) determining the sequence of the nucleic acid from the identified nucleotides (page 15, line 3 and page 15-line 30-page 16, line 2; where determining the identity of fragments (which comprise nucleotides) in the order in which they are released from a nucleic acid is determining the sequence).

Regarding claim 2, Kneipp teaches identification of single molecules of unlabeled nucleotides by Raman spectroscopy, (page 8, lines 2-9).

Regarding claims 4 and 25, Kneipp inherently teaches that “multiple nucleic acid molecules of the same or different sequence are sequenced simultaneously” (see page 15). The DNA or RNA sample from which nucleotides are released by exonuclease treatment, absent an explicit statement to the contrary, is inherently comprised of multiple nucleic acid molecules of the same sequence which are fragmented and sequenced simultaneously.

Regarding claims 6 and 22, Kneipp teaches the method of claim 1, wherein the nucleotides are identified by surface enhanced Raman spectroscopy (SERS) (page 14, lines 29-31).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use SERS for detection of released nucleotides in the method of Dorre. Kneipp particularly pointed out the advantages of substituting Raman spectroscopy (specifically, SERS) for fluorescence spectroscopy, namely the ability to maintain a high level of sensitivity and specificity while eliminating the need to use fluorescently labeled nucleotides (page 12, line 27 – page 13, line 7). The ordinary practitioner would have been motivated by the teachings of Kneipp to substitute SERS for fluorescence detection in order to eliminate the need to rely on the detection of labeled nucleotides. The ordinary user would also have found further motivation to

use a label-free detection method in the teachings of Dorre. Dorre taught that fluorescent labeling of nucleic acids was difficult due to the differential rate of label incorporation by DNA polymerase and also that labeling of every nucleotide or even every base was not currently possible (see page 143, col. 2). Therefore, the label-free SERS detection method of Kneipp would have held particular appeal to the ordinary practitioner of the method of Dorre, and combination of the teachings of Dorre and Kneipp would have resulted in the instant claims 1-4, 6, 22-23, 25, and 26.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorre et al. (Bioimaging (1997) 5: 139-152) in view of Kneipp et al. (WO 99/44045) and further in view of Hunkapillar et al. (USPN 5942609).

The combined teachings of Dorre and Kneipp result in the instant claim 1, as discussed above.

Dorre teaches immobilization via a non-covalent biotin-streptavidin interaction (Fig. 1), but neither Dorre nor any of the other previously cited references teach covalent immobilization of the nucleic acid.

Hunkapillar teaches that nucleic acids may be immobilized covalently to a surface, such as a polystyrene bead, as an alternative to biotin-streptavidin coupling (column 9, lines 36-50).

It would have been prima facie obvious for the ordinary practitioner of the sequencing method resulting from the combined teachings of Dorre and Kneipp to covalently link the nucleic acid to the surface. Hunkapillar taught general methods of nucleic acid immobilization to surfaces, including beads similar to those taught by Dorre. Hunkapillar taught covalent and

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non-covalent immobilization, and expressly stated that covalent coupling was preferable (col. 9, lines 36-37), thereby motivating the ordinary practitioner to substitute covalent coupling for the biotin-streptavidin linkage taught by Dorre and resulting in the instantly claimed method.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorre et al. (Bioimaging (1997) 5: 139-152) in view of Kneipp et al. (WO 99/44045) and further in view of Vo-Dinh (Trends in Analytical Chemistry (1998) 17: 557-582) and further in view of Elghanian et al. (Science (1997) 277: 1078 – 1081).

The combined teachings of Dorre and Kneipp result in the instant claim 1, as discussed above.

Neither Dorre nor Kneipp teach attachment of nanoparticles to the 3' end of the nucleic acid.

Vo-Dinh teaches that gold and silver nanoparticles (examples listed in Figure 1 and Table 1) are SERS-active substrates that act to enhance the observed Raman signal with “substantially improved reproducibility and quantification” (page 570 column 2). Vo-Dinh also teaches attachment of nucleic acids to nanoparticles (page 577, the SERGen probe), but does not provide further details as to which end of the nucleic acid is attached.

Mirkin teaches covalent attachment of gold nanoparticles to either the 5' end or the 3' end of nucleic acids via a thiol linkage (page 1078, column 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to substitute nanoparticles for the polystyrene beads in the method resulting from the combined teachings of Dorre and Kneipp. Vo-Dinh expressly taught several examples of

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nanoparticles that were useful as SERS-active substrates (see Figure 1 and Table 1), and particularly pointed out that these materials enhanced the observed Raman signal with “substantially improved reproducibility and quantification” (page 570 column 2). These teachings of Vo-Dinh would have provided strong motivation for the ordinary practitioner to substitute SERS-active nanoparticles for the SERS-inactive polystyrene beads used in the Dorre method in order to obtain a stronger, more reproducible signal. Since Elghanian taught a method of attaching nanoparticles to either end of a nucleic acid (see column 3, page 1078), the ordinary practitioner would have been motivated to attach the nanoparticles to either the 5’ end or the 3’ end of the nucleic acid, as required for the specific application. Since the combined method of Dorre and Kneipp comprises release of nucleotides from the 5’ end of a 3’ immobilized nucleic acid, the ordinary practitioner would have been motivated to attach the nanoparticles to the 3’ end in order to successfully conduct the method. Therefore, the ordinary practitioner of the sequencing method resulting from the combined teachings of Dorre and Kneipp, would have been motivated to attach nanoparticles to the 3’ end of the nucleic acid to be sequenced, as suggested by Vo-Dinh and Elghanian, thus resulting in the instantly claimed method.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorre et al. (Bioimaging (1997) 5: 139-152) in view of Kneipp et al. (WO 99/44045) and further in view of Chen et al. (Chemical Physics Letters (1984) 108(1): 32-38).

The combined teachings of Dorre and Kneipp result in claim 22, as discussed above.

Neither Dorre nor Kneipp teaches the use of LiCl as the alkali-metal halide salt.

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Chen teaches alkali-metal halide salt solutions including NaCl, LiCl, HCl, MgCl₂, NaBr, CsI, RbI, LiI, KCN, and NaN₃ are SERS-active solutions (page 32, col. 1 and also the abstract).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to substitute LiCl for MgCl₂ in the combined method resulting from the teachings of Dorre and Kneipp. The ordinary user would also have been motivated by the teachings of Chen to use any known SERS-active solution such as the LiCl that Chen taught was SERS-active to enhance the observed Raman signal. Since Chen taught that several alkali-metal halide salt solutions (including LiCl and MgCl₂) were SERS-active, the ordinary user would have recognized the equivalence of these different solutions for enhancing the SERS signal, and would, therefore, have been motivated to substitute any of the disclosed alkali-metal halide salt solutions in the combined method of Dorre and Kneipp, thus resulting in the instantly claimed methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

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ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-9, 11, 12, 17-19, 22-24, and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,972,173 in view of Chen et al. (Chemical Physics Letters (1984) 108(1): 32-38).

Claims 1 and 5 of the '173 patent recite a specific embodiment of the method of the instant claim 7 with the exception that the '173 patent does not recite the use of an alkali-halide metal salt, such as LiCl. The limitations recited in the instant claims 8-9 are recited in claims 1 and 6 of the '173 patent. The limitations of the instant claim 17 are recited in claim 7 of the '173 patent. The limitations of the instant claims 18-19 are recited in claims 1 and 2 of the '173 patent.

Claims 1 and 3 of the '173 patent also recite a specific embodiment of the method of the instant claim 22 with the exception that the '173 patent does not recite the use of an alkali-metal halide salt, such as LiCl. The limitations recited in the instant claim 26 are recited in claim 4 of the '173 patent.

As noted above, the '173 patent does not teach the use of an alkali-halide salt solution, such as LiCl.

Chen teaches that alkali-metal halide salt solutions including NaCl, LiCl, HCl, MgCl₂, NaBr, CsI, RbI, LiI, KCN, and NaN₃ are SERS-active solutions (page 32, col. 1 and also the abstract).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use a SERS-active alkali-halide salt solution, such as LiCl, in the method recited in the '173 patent. Chen taught that several alkali-metal halide salt solutions (including LiCl and MgCl₂) were SERS-active (abstract and col. 1 of page 32), thereby providing motivation for the ordinary practitioner to use such a solution in order to further enhance the observed Raman signal. The teachings recited in claims 1-7 of the '173 patent combined with the teachings of Chen result in the methods recited in the instant claims 7-9, 11, 12, 17-19, 22-24, and 26.

Claim 13 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 6,972,173 in view of Chen et al. (Chemical Physics Letters (1984) 108(1): 32-38) and further in view of Fritzsche et al. (USPN 6,878,539 B1; this document has been used as the English translation of the German document published July 6, 2000 as WO 00/39325).

The combined teachings of the '173 patent and Chen are discussed above.

The claims of the '173 patent do not recite the use of GOP as a linker.

Fritzsche teaches that GOP may be used to covalently attach nucleic acids to nanoparticles (column 9, line 61 – column 11, line 3).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use a GOP as a linker, in the method recited in the '173 patent. Fritzsche taught that this linker was useful for covalent immobilization of nucleic acids to nanoparticles (see above), thereby providing motivation for the ordinary practitioner to use such a linker to attach the

nucleic acid to nanoparticles. The teachings recited in claims 1 and 5 of the '173 patent combined with the teachings of Fritzsche result in the method recited in the instant claim 13.

Claims 20 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 5 of U.S. Patent No. 6,972,173 in view of Chen et al. (Chemical Physics Letters (1984) 108(1): 32-38) and further in view of Vo-Dinh et al. (Trends in Analytical Chemistry, (1998) 17: 557-582).

The combined teachings of the '173 patent and Chen are discussed above.

The '173 patent recites use of a metal-coated microfluidic channel (see claim 2), and the use of silver nanoparticles (see claim 1) but does not recite that the metal of the microfluidic channel is silver, gold, platinum, copper, or aluminum.

Vo-Dinh teaches that silver, gold, copper, aluminum, and platinum are all SERS-active metals (page 561, col. 1).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to select silver, gold, copper, aluminum, or platinum as the metal coating in the metal-coated microfluidic channel recited in the '173 patent. Vo-Dinh taught that all of these metals were SERS-active (page 561, col. 1), and therefore, useful for coating channels and other microstructures used in SERS methodology. The ordinary practitioner would have been motivated by the teachings of Vo-Dinh to use any of the claimed SERS-active metals for coating the metal-coated microfluidic channel of the '173 patent in order to maximize the observed SERS signal. The teachings recited in claims 1, 2, and 5 of the '173 patent combined with the teachings of Vo-Dinh result in the methods recited in the instant claims 20 and 21.

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Claims 22-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12 and 15 of copending Application No. 10/108,128 in view of Chen et al. (Chemical Physics Letters (1984) 108(1): 32-38).

Claims 12 and 15 of the '128 application recite a specific embodiment of the method recited in the instant claim 22, with the exception that the use of an alkali-halide metal salt solution is not recited in the claims of the '128 application.

Chen teaches that alkali-metal halide salt solutions including NaCl, LiCl, HCl, MgCl₂, NaBr, CsI, RbI, LiI, KCN, and NaN₃ are SERS-active solutions (page 32, col. 1 and also the abstract).

It would have been prima facie obvious for one of ordinary skill in the art at the time of invention to use a SERS-active alkali-halide salt solution, such as LiCl, in the method recited in the '128 application. Chen taught that several alkali-metal halide salt solutions (including LiCl) were SERS-active (abstract and col. 1 of page 32), thereby providing motivation for the ordinary practitioner to use such a solution in order to further enhance the observed Raman signal. The teachings recited in claims 12 and 15 of the '128 application combined with the teachings of Chen result in the methods recited in the instant claims 22-24.

This is a provisional obviousness-type double patenting rejection.

Response to Amendment

Claim objections

Applicant's amendment to claim 23 is noted. The previously made objection is withdrawn.

Response to Arguments

35 USC § 112, 2nd paragraph rejections:

Applicant's arguments, see page 7, filed May 27, 2006, with respect to the rejection of claims 1-21 under §112, 2nd paragraph, have been fully considered and are persuasive. The cancellation of claims 14 and 15 and amendment of claims 1, 4, 6, and 7 have rendered the previously made rejections moot, and therefore, they are withdrawn.

35 USC § 112, 1st paragraph rejections:

Applicant's arguments, see page 8, filed May 27, 2006, with respect to the rejection of claims 7-21 and 24 under §112, 1st paragraph, have been fully considered and are persuasive. The cancellation of claims 14 and 15 and amendment of claims 7 and 24 have rendered the previously made rejections moot, and therefore, they are withdrawn.

35 USC § 102 rejections:

Applicant's arguments, see pages 8-9, filed May 27, 2006, with respect to the rejection of claims 1, 2, 4, and 6 under § 102(b), have been fully considered and are persuasive. Kneipp no

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longer teaches all of the elements of the amended claim 1, and therefore, the previously made rejection is withdrawn.

35 USC § 103 rejections:

Applicant's arguments with respect to claims 22-23 and 25-26 have been considered but are moot in view of the new ground(s) of rejection presented above.

Double Patenting rejections:

Applicant's arguments, see page 11, filed May 27, 2006, with respect to the rejection of claims 22 and 24-26 as claiming the same invention as recited in claims 15 and 17-19 of Application No. 11/235,796 (statutory double patenting), have been fully considered and are persuasive. Since claims 1-23 of 11/235,796 have been cancelled by preliminary amendment, the rejection is moot, and therefore, is withdrawn.

Applicant's arguments, see page 12, filed May 27, 2006, with respect to the rejection of claims 7, 8, 11, 12, and 17-19 as claiming an obvious variant of the invention recited in claims 1, 3-5, 8, 11, and 12 of Application No. 11/235,796 (obvious double patenting), have been fully considered and are persuasive. Since claims 1-23 of 11/235,796 have been cancelled by preliminary amendment, the rejection is moot, and therefore, is withdrawn.

Applicant's arguments, see pages 11-12, with respect to the rejection of claims 22, 23, 25, and 26 under the judicially created doctrine of obvious double patenting over claims 1 and 3-6 of USPN 6,972,173 have been considered but are moot in view of the new ground(s) of rejection presented above.

Applicant's arguments, see page 12, with respect to the rejection of claims 7-9, 17-19, and 22-25 under the judicially created doctrine of obvious double patenting over claims 1, 2, 5, 6, 12, 14, 15, and 18 of co-pending Application No. 10/108,128 have been considered but are moot in view of the new ground(s) of rejection presented above.

Conclusion

No claims are currently allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Angela Bertagna
Patent Examiner
Art Unit 1637

amb



JEFFREY FREDMAN
PRIMARY EXAMINER

6/29/06